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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Furazolidone Aerosol Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, a Division of American Cyanamid Co. The supplemental NADA provides for removal of that portion of the approval reflecting topical cattle use of furazolidone aerosol powder.

DATES: This regulation is effective (*insert date of publication in the* **Federal Register**).

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6642.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, a Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, is the sponsor of NADA 32–319 for Furox (furazolidone) aerosol powder for use in dogs, horses, ponies, and cattle. The sponsor filed a supplemental NADA requesting removal of topical ocular use of the product in cattle. The supplemental NADA is approved as of November 29, 1999, and the regulations are amended in 21 CFR 524.1005(b)(1), (c)(2)(iii), and (c)(3) to reflect the approval.

The regulations in § 524.1005(b)(1) (21 CFR 524.1005(b)(1)) indicate that Pfizer, Inc., is sponsor of NADA 32–319 for use of a 10 percent furazolidone aerosol powder in dogs, horses,

and cattle. The NADA had been acquired by Fort Dodge Animal Health, a Division of American Cyanamid Co. At this time, the regulation is amended in § 524.1005(b) to reflect the sponsor change.

Approval of this supplemental NADA provides for removal of a cattle use. It does not affect the safety or effectiveness data in the application. Therefore, a freedom of information summary is not required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1005 is amended by revising paragraphs (b)(1) and (c)(3) and by removing and reserving paragraph (c)(2)(iii) to read as follows:

§ 524.1005 Furazolidone aerosol powder.

* * * * *

(b) * * *

(1) See No. 053501 in § 510.600(c) of this chapter for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

* * * * *

(c) * * *

(2) * * *

(iii) [Reserved]

(3) *Limitations*. For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug once or twice daily, and repeat treatment as required. Use only as recommended by a veterinarian in treatment of puncture wounds, wounds requiring surgical debridement or suturing, those of a chronic nature involving proud flesh, generalized and chronic

infections of the skin, and those skin conditions associated with intense itching. If redness, irritation, or swelling persists or increases, discontinue use and consult a veterinarian. Not for use in horses intended for food.

Dated: June 15, 2000
June 15, 2000

Andrew J. Beaulieu
Deputy Director
Center for Veterinary Medicine

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